

HAND SANITIZER- alcohol aerosol, spray
Cosmetic Specialty Labs, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Aloe Barbadensis Leaf Juice.
- c. Caprylyl Glycol.
- d. Glycerin.
- e. Phenoxyethanol.
- f. Polysorbate-20.
- g. Purified Water.
- h. Tocopheryl Acetate.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient

SD Alcohol 40 75%

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame. For external use only.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Center right away.

Directions

- Use enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110F (43C)
- May discolor fabrics or surfaces

Inactive ingredients

Aloe Barbadensis Leaf Juice, Caprylyl Glycol, Fragrance, Glycerin, Phenoxyethanol, Polysorbate-20, Purified Water, Tocopheryl Acetate.

Package Label - Principal Display Panel

NDC:58133-959-62

HAND SANITIZER

alcohol aerosol, spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58133-959 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| WATER (UNII: 059QF0K00R) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| GLYCERIN (UNII: PDC6A3C00X) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58133-959-62 | 178 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/30/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 08/30/2021 | |

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---|
| Cosmetic Specialty Labs, Inc. | | 032973000 | manufacture(58133-959) , label(58133-959) , pack(58133-959) , analysis(58133-959) |

Revised: 8/2021

Cosmetic Specialty Labs, Inc.